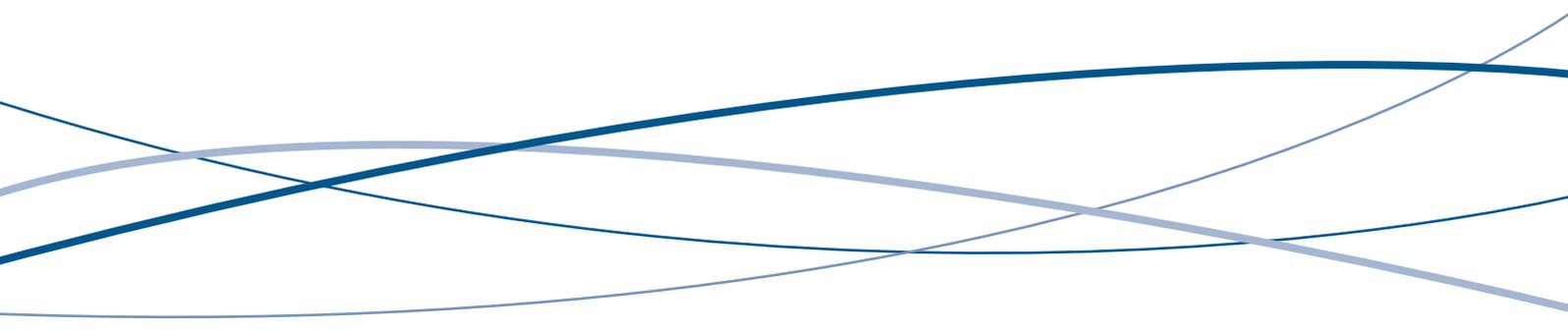


**A promise to learn  
– a commitment to act**



## **Improving the Safety of Patients in England**

**National Advisory Group on the  
Safety of Patients in England**

August 2013

# Contents

<b>Executive Summary</b>	<b>4</b>
<b>A promise to learn - a commitment to act: Improving the safety of patients in England</b>	<b>7</b>
<b>Recommendations</b>	<b>13</b>
<b>I. The overarching goal</b>	<b>14</b>
<b>II. Leadership</b>	<b>15</b>
<b>III. Patient and public involvement</b>	<b>18</b>
<b>IV. Staff</b>	<b>21</b>
<b>V. Training and capacity building</b>	<b>24</b>
<b>VI. Measurement and transparency</b>	<b>27</b>
<b>VII. Structures and regulation</b>	<b>30</b>
<b>VIII. Enforcement</b>	<b>33</b>
<b>IX. Moving forward</b>	<b>36</b>
<b>Annex A: A note on our methodology</b>	<b>39</b>
<b>Annex B: Letters</b>	<b>40</b>
Letter to Senior Government Officials and Senior Executives in the Health Service	40
Letter to the people of England	42
Letter to the clinicians, managers, and all staff of the NHS	44
<b>Annex C: List of Advisory Group Members</b>	<b>46</b>

# Executive Summary

*Place the quality of patient care, especially patient safety, above all other aims.*

*Engage, empower, and hear patients and carers at all times.*

*Foster whole-heartedly the growth and development of all staff, including their ability and support to improve the processes in which they work.*

*Embrace transparency unequivocally and everywhere, in the service of accountability, trust, and the growth of knowledge.*

At its core, the NHS remains a world-leading example of commitment to health and health care as a human right – the endeavour of a whole society to ensure that all people in their time of need are supported, cared for, and healed. It is a fine institution. But the events at Mid Staffordshire have triggered a need to re-examine what the NHS does and determine how it can improve further. The only conceivably worthy honour due to those harmed is to make changes that will save other people and other places from similar harm.

Our job has been to study the various accounts of Mid Staffordshire, as well as the recommendations of Robert Francis and others, to distil for Government and the NHS the lessons learned, and to specify the changes that are needed.

The following are some of the problems we have identified:

- Patient safety problems exist throughout the NHS as with every other health care system in the world.
- NHS staff are not to blame – in the vast majority of cases it is the systems, procedures, conditions, environment and constraints they face that lead to patient safety problems.
- Incorrect priorities do damage: other goals are important, but the central focus must always be on patients.
- In some instances, including Mid Staffordshire, clear warning signals abounded and were not heeded, especially the voices of patients and carers.
- When responsibility is diffused, it is not clearly owned: with too many in charge, no-one is.
- Improvement requires a system of support: the NHS needs a considered, resourced and driven agenda of capability-building in order to deliver continuous improvement.
- Fear is toxic to both safety and improvement.

To address these issues the system must:

- Recognise with clarity and courage the need for wide systemic change.
- Abandon blame as a tool and trust the goodwill and good intentions of the staff.
- Reassert the primacy of working with patients and carers to achieve health care goals.
- Use quantitative targets with caution. Such goals do have an important role *en route* to progress, but should never displace the primary goal of better care.

- Recognise that transparency is essential and expect and insist on it.
- Ensure that responsibility for functions related to safety and improvement are vested clearly and simply.
- Give the people of the NHS career-long help to learn, master and apply modern methods for quality control, quality improvement and quality planning.
- Make sure pride and joy in work, not fear, infuse the NHS.

**The most important single change in the NHS in response to this report would be for it to become, more than ever before, a system devoted to continual learning and improvement of patient care, top to bottom and end to end.**

**We have made specific recommendations around this point, including the need for improve training and education, and for NHS England to support a network of safety improvement collaboratives to identify and spread safety improvement approaches across the NHS.**

Our ten recommendations are as follows:

1. The NHS should continually and forever reduce patient harm by embracing wholeheartedly an ethic of learning.
2. All leaders concerned with NHS healthcare – political, regulatory, governance, executive, clinical and advocacy – should place quality of care in general, and patient safety in particular, at the top of their priorities for investment, inquiry, improvement, regular reporting, encouragement and support.
3. Patients and their carers should be present, powerful and involved at all levels of healthcare organisations from wards to the boards of Trusts.
4. Government, Health Education England and NHS England should assure that sufficient staff are available to meet the NHS's needs now and in the future. Healthcare organisations should ensure that staff are present in appropriate numbers to provide safe care at all times and are well-supported.
5. Mastery of quality and patient safety sciences and practices should be part of initial preparation and lifelong education of all health care professionals, including managers and executives.
6. The NHS should become a learning organisation. Its leaders should create and support the capability for learning, and therefore change, at scale, within the NHS.
7. Transparency should be complete, timely and unequivocal. All data on quality and safety, whether assembled by government, organisations, or professional societies, should be shared in a timely fashion with all parties who want it, including, in accessible form, with the public.
8. All organisations should seek out the patient and carer voice as an essential asset in monitoring the safety and quality of care.
9. Supervisory and regulatory systems should be simple and clear. They should avoid diffusion of responsibility. They should be respectful of the goodwill and sound intention of the vast majority of staff. All incentives should point in the same direction.
10. We support responsive regulation of organisations, with a hierarchy of responses. Recourse to criminal sanctions should be extremely rare, and should function primarily as a deterrent to wilful or reckless neglect or mistreatment.

The NHS in England can become the safest health care system in the world. That will require unified will, optimism, investment, and change. Everyone can and should help. And, it will require a culture firmly rooted in continual improvement. Rules, standards, regulations and enforcement have a place in the pursuit of quality, but they pale in potential compared to the power of pervasive and constant learning.

# A promise to learn – a commitment to act:

## Improving the safety of patients in England

We do not need to recite the details of the tragedy of Mid-Staffordshire in this report. Many people probably died from avoidable causes, and many more suffered unnecessary indignities and harm. The details are catalogued for posterity in Robert Francis's historic report; and the story is now indelibly part of the history of the NHS in England<sup>1</sup>.

The only conceivably worthy honour due to those harmed is to make changes that will save other people and other places from similar harm. It would add tragedy to tragedy if the nation failed to learn from what happened, and to put those lessons to work. Without ever forgetting what has happened, **the point now is to move on.**

Beyond doubt the NHS can do that, perhaps better than any other health care system in the world. The wave of concern that led to commissioning this report ought not to obscure the enormous strengths of the NHS, its positive achievements, or its even greater promise.

In its core and concept, the NHS has been and remains a world-leading example of commitment to health and health care as a human right – the endeavour of a whole society to ensure that all people in their time of need are supported, cared for, and healed. The vast majority of those who serve in the NHS – clinicians, staff, managers, executives, and boards, contractors and partners – try every day to help to the very best of their abilities, and with deep and appropriate pride in their mission. This Advisory Group recommends important changes that we believe will lead to an even better and safer NHS, but we do not thereby suggest that the NHS has fundamentally lost its way. It is a fine institution that can and should now become much better.

Our job from March 2013 through to July 2013 has been to study the various available accounts of Mid Staffordshire, as well as the recommendations of Robert Francis and others, to distil for Government and the NHS the lessons learned, and to **specify the changes that are needed.**

In announcing our work, the Prime Minister boldly suggested that we might help the NHS achieve “zero harm.” We welcomed this ambitious call, but also agreed from the beginning that even the aims for improvement – what the NHS should strive to achieve and how quickly – would be subjects for our deliberations, and not set by others. We were formed as, and we remain, an independent Advisory Group, relying on our best thinking, not on outside instruction, for our findings.

We cannot and do not claim comprehensiveness in what we recommend. We knew that we would choose to remain silent on many of the Francis Report's 290 recommendations, and that we would not try to comment on everything important for the NHS to do next in the wake of Mid Staffordshire. Further, while we

---

<sup>1</sup> This report is focused on the NHS in England and where we say 'NHS' we are referring to the NHS in England. However, the lessons are applicable to other healthcare systems, both within the rest of the UK and worldwide.

wholeheartedly support changes in the configuration of services and detailed processes of care that will improve safety and quality, we do not in this report attempt to prescribe those changes. That is better left to commissioners and to the people who give care; they, not we, are the experts in care delivery.

We believe that the actions we propose are necessary, but they are not sufficient to secure a robust future for safety in the NHS. We are only one among many who will together help establish and maintain a better course. Indeed, several fine reports and studies overlapping our charge have appeared during the period of our work. Important among them is the recent Keogh Review, whose recommendations we endorse.

## The problems

Motivating our recommendations are findings that we gathered from prior reports (those of Robert Francis and others), the statements of patients and other experts, the research evidence, and our own experience. Among the most important of these findings are the following:

1. **Patient safety problems exist throughout the NHS:** The Mid Staffordshire tragedy may be the most notorious recent lapse in care in the English NHS, but it is not unique. A few other trusts show signs that warrant prompt further scrutiny and, when appropriate, intervention, such as the Keogh review has recently ably modelled. More generally, like every other health care system in the world, the NHS experiences repeated defects in patient safety, and too many patients and carers suffer as a result. We feel strongly that, as for all healthcare systems, **the whole NHS should strengthen patient safety now and into the future.**
2. **NHS staff are not to blame:** Neither at Mid Staffordshire, nor more widely, is it scientifically justifiable to blame the staff of the NHS or label them as uncaring, unskilled, or culpable. A very few may be exceptions, but **the vast majority of staff wish to do a good job, to reduce suffering and to be proud of their work.** Good people can fail to meet patients' needs when their working conditions do not provide them with the conditions for success.
3. **Incorrect priorities do damage:** The Mid Staffordshire tragedy and wider quality defects in the NHS seem traceable in part to a loss of focus by at least some leaders on both excellent patient care and continual improvement as primary aims of the NHS (or to a misinterpretation by providers of the intent of leaders). In some organisations, in the place of **the prime directive, "the needs of the patient come first"**, goals of (a) hitting targets and (b) reducing costs have taken centre stage. Although other goals are also important, where the central focus on patients falters, signals to staff, both at the front line and in regulatory and supervisory bodies, can become contaminated. Listening to and responding to patients' needs then become, at best, secondary aims. Bad news becomes unwelcome and, over time, it is too often silenced. Under such conditions organisations can hit the target, but miss the point.
4. **Warning signals abounded and were not heeded:** Information on the deterioration of the quality of care at Mid-Staffordshire was abundant. It appeared in both narration (complaints from staff, carers and patients) and quantitative metrics (such as significantly high adjusted mortality rates compared with rates throughout England). **Loud and urgent signals were muffled and explained away.** Especially costly was the muffling of the voices of patients and carers who took the trouble to complain but whose complaints were too often ignored.
5. **Responsibility is diffused and therefore not clearly owned:** Responsibility for oversight and remedy for quality and safety concerns was, and is still to some extent, diffused in the NHS in England, with that responsibility divided among many agencies, and with unclear or at times non-existent lines of

coordination, communication, pattern-recognition and follow-up for action. **When so many are in charge, no one is.**

6. **Improvement requires a system of support:** The capability to measure and continually improve the quality of patient care needs to be taught and learned or it will not exist. The NHS needs a considered, resourced and driven agenda of capability-building in order to generate the capacity for continuous improvement. That investment in human development is absolutely necessary if, when alarms ring as they did in Mid Staffordshire, people with their hands on the steering wheel are to have the knowhow to diagnose and fix the problems. **The most important single change in the NHS in response to this report would be for it to become, more than ever before, a system devoted to continual learning and improvement of patient care, top to bottom and end to end.**
7. **Fear is toxic to both safety and improvement:** Fear impedes improvement in complex human systems. Time and again, we see the harvest of fear in the Mid Staffordshire story, a vicious cycle of over-riding goals, misallocation of resources, distracted attention, consequent failures and hazards, reproach for goals not met, more misallocation and growing opacity as dark rooms with no data came to look safer than ones with light. **“Better not to know” became the order of the day.** A symptom of this cycle is the gaming of data and goals; if the system is unable to *be* better, because its people lack the capacity or capability to improve, the aim becomes above all to *look* better, even when truth is the casualty.

Even while asserting unblinkingly what is amiss, it is important to notice and celebrate the strengths of the NHS. Big changes are needed, but **we do not believe that the NHS is unsound in its core.** On the contrary, its achievements are enormous and its performance in many dimensions has improved steadily over the past two decades.

We have the data. Waiting times are shorter than 15 years ago, cardiovascular care and outcomes are far better, cancer care is improving fast and healthcare-acquired infection rates have plummeted. Stroke care in London reached world-class levels. From the beginning of this century, the UK has seen unprecedented investments in training staff in quality improvement, in measuring service and outcomes and in fostering collaborative improvement projects among hundreds of hospitals and ambulatory practices. Those investments have paid off. NHS experts have pioneered patient-driven health care designs, in new models of “productive wards” and “productive operating theatres,” and in patient safety research. Innovation is abundant; the barriers have been more to spread of effective new models than to their creation. Most impressive of all, perhaps, has been the consistent dedication to helping their patients among the vast majority of NHS clinicians – doctors, nurses, pharmacists, allied health professionals, mental health professionals and many more – as well as non-clinical staff.

Society, in general, and leaders and opinion formers, in particular, (including national and local media, national and local politicians of all parties, and commentators) have a crucial role to play in shaping a positive culture that, building on these strengths, can realise the full potential of the NHS. When people find themselves working in a culture that avoids a predisposition to blame, eschews naïve or mechanistic targets, and appreciates the pressures that can accumulate under resource constraints, they can avoid the fear, opacity, and denial that will almost inevitably lead to harm.

In pursuit of such a culture, as the leaders whom we encountered in our work know, a measured and balanced response, anchored in science and evidence, serves the nation well. Even while leaders speak out clearly and with courage, as they should, when things go wrong, it is helpful to avoid drama, accusation and overstatement either in the Mid Staffordshire case or in other cases of lapses in patient safety. No single person, party, or administration caused the problems that need to be solved, and everyone can help guide the

next steps if they work together. Likewise, the media's role in uncovering and highlighting genuine problems has been and will remain invaluable, but, at its best, the media is also a key resource for public education and the encouragement of improvement.

## The solutions

This litany of problems is, of course, tough to read. However, these concerns are not unique to the NHS; they occur in all large health care systems. Recognising them is the first step toward the repair; knowing what is going wrong gives us the opportunity to set things right.

Set out below are the principles of action that have guided us in our choice of recommendations:

1. **Recognise with clarity and courage the need for wide systemic change:** All improvement begins with clear recognition and acknowledgement of the need to improve. Building a better, safer NHS will benefit from that recognition and involvement from everyone who has a contribution to make to health and care – not just the directly funded NHS, but also contractors and partners, large and small healthcare businesses, social enterprises and voluntary organisations, local authorities, privately funded carers, and, of course, patients, carers and communities. Everyone.
2. **Abandon blame as a tool.** Trust the goodwill and good intentions of the staff, and help them achieve what they already want to achieve: better care and the relief of human suffering. Misconduct can occur and it deserves censure. But, errors are not misconduct and do not warrant punishment:
3. **Reassert the primacy of working with patients and carers to set and achieve health care goals.** Patient safety is better served when patients and carers are as actively engaged in healthcare as they want to be:
4. **Use quantitative targets with caution.** Goals in the form of such targets can have an important role *en route* to progress, but should never displace the primary goal of better care. When the pursuit of targets becomes, for whatever reason, the overriding priority, the people who work in that system may focus too narrowly. Financial goals require special caution; they reflect proper stewardship and prudence, but are only a means to support the mission of the NHS: healing:
5. **Recognise that transparency is essential and expect and insist on it at all levels and with regard to all types of information** (other than personal data). The most valuable information of all is information on risks and on things that have gone wrong; and among the most valuable sources of information are the reports and voices of patients, carers and staff. Everyone, including staff, should be free to state openly their concerns about patient safety without reprisal, and there is no place for compromise agreements ("gagging clauses") that prevent staff discussing safety concerns:
6. **Ensure that responsibility for functions related to safety and improvement are vested clearly and simply** in a thoroughly comprehensible set of agencies, among whom full cooperation is, without exception, expected and achieved:
7. **Give the people of the NHS – top to bottom – career-long help to learn, master and apply modern methods for quality control, quality improvement and quality planning.** The NHS has an obligation to assure their growth and support:
8. **Make sure pride and joy in work, not fear, infuse the NHS.**

In sum, the recommendations below reflect our view that the quality of patient care should come before all other considerations in the leadership and conduct of the NHS, and that patient safety is the keystone dimension of quality. The pursuit of continually improving safety should permeate every action and level in the NHS.

The Francis Report recommended numerous types of new regulation. Regulation, especially using intelligent inspection by experts, does have an important role in setting out what is expected, monitoring the extent to which those expectations are met, and taking action when they are not met. Clear and prompt response to alarming signals, such as have now been investigated in the Keogh study of some hospitals with significantly high mortality rates, is crucial for quality control.

However, regulation alone cannot solve the problems highlighted by Mid Staffordshire. Neither quality assurance nor continual improvement can be achieved through regulation based purely on technically specific standards, particularly where a blunt assertion is made that any breach in them is unacceptable.

**In the end, culture will trump rules, standards and control strategies every single time, and achieving a vastly safer NHS will depend far more on major cultural change than on a new regulatory regime.**

As a universal healthcare system, free at the point of use, with common goals, structures and systems, the NHS is unique in the world, and can do what no other system can. It has the potential to be the safest healthcare system in the world. The best responses to the Francis Report, the best routes to badly needed improvements, will build on the strengths of the NHS, not ignore them or take them for granted. This will take time to bear fruit and require many years of effort, many messages and many deeds. There is no easy fix, but the prize is worth the price.

## A note on the nature of quality and patient safety

To help readers understand the recommendations that follow, we need to describe our perspective on quality and how this relates to safety and the causes of harm.

Many modern industries define “quality” as “*the degree to which a system of production meets (or exceeds) the needs and desires of the people it serves*”. An effective quality management system includes *quality control* (to keep sound processes reliable on a daily basis), *quality improvement* (to decrease variation within and among NHS organisations so that the best becomes the norm) and *quality planning* (especially fostering innovative care models that can deliver better outcomes at lower cost).

Lord Darzi defined quality for the NHS as comprising three dimensions:

- Safety (avoiding harm from the care that is intended to help).
- Effectiveness (aligning care with science and ensuring efficiency).
- Patient-experience (including patient-centeredness, timeliness and equity).

All these dimensions count, but one among them – safety – emerges repeatedly as the most expected; patients, families and the public expect that the people and organisations that exist to help them will not hurt them. “*First do no harm*” is not just a slogan in health care; it is a central aim.

Yet, health care necessarily involves some risk. In seeking the benefits of modern medicine, patients may reasonably choose treatments that involve risk or cause side effects. People have chemotherapy knowing that

the effects are unpleasant. They accept the risk of the treatment in hope of cure or to prolong life. And, new treatments, even wondrous ones, always bring new threats to safety.

In addition to risks inherent in some treatments, there is also inescapable tension between the pursuit of safety and the pursuit of other healthcare priorities. If resources were infinite, many risks could be eliminated. But, resources are not infinite. Achieving a proper balance between risks and resources requires constant vigilance against reductions in resources – such as time, people or consumables – that raise risk to unnecessary and unacceptable levels. People at all levels of care and in all roles need to acknowledge this tension, so that dialogue remains clear, mature and open about how much risk to accept in pursuit of goals other than safety.

Even though hazards in care cannot be eliminated, harms to patients can be and should be reduced continually, everywhere and forever. The fight for safety is a never-ending struggle against entropy, engaged tirelessly and with focus against an enemy that continually emerges and re-emerges.

We distinguish three types of unnecessary risk of harm: risk of harm due to neglect or wilful misconduct; risk of harm due to failures in the system; and risk of harm from error. They are not the same. As Robert Francis has unequivocally shown, some harm is, indeed, due to neglect or to wilful misconduct. These rare sources of harm should be distinguished from the far more common kind: errors made by well-intentioned people or arising from failures in the system. Improving the reliability and safety of healthcare systems is a critical task for leaders. They need to differentiate carefully between error and neglect or wilful misconduct.

Error and neglect or wilful misconduct warrant different responses. Even apparently simple human errors almost always have multiple causes, many beyond the control of the individual who makes the mistake. Therefore, it makes no sense at all to punish a person who makes an error, still less to criminalise it. The same is true of system failures that derive from the same kind of multiple unintentional mistakes. Because human error is normal and, by definition, is unintended, well-intentioned people who make errors or are involved in systems that have failed around them need to be supported, not punished, so they will report their mistakes and the system defects they observe, such that all can learn from them. On the other hand, harm caused by neglect or wilful misconduct does warrant sanctions in health care, just as it does in other settings.

# Recommendations

The recommendations that follow are grouped into nine categories:

- I. The Overarching Goal
- II. Leadership
- III. Patient and Public Involvement
- IV. Staff
- V. Training and Capacity-Building
- VI. Measurement and Transparency
- VII. Structures
- VIII. Enforcement
- IX. Moving Forward

In the first eight sections, we provide the key recommendations and a brief narrative. These are followed by our suggestions for specific actions by named actors. In the "Moving Forward" section, we offer some summary views and suggest the highest priority actions.

# I. The overarching goal

## Recommendation

- 1. The NHS should continually and forever reduce patient harm by embracing wholeheartedly an ethic of learning.**

*Patient safety should be the ever-present concern of every person working in or affecting NHS-funded care. The quality of patient care should come before all other considerations in the leadership and conduct of the NHS, and patient safety is the keystone dimension of quality.*

*Be in no doubt, we are herein advocating a monumental challenge, which will require unprecedented acts of will by the political and executive leadership of the NHS, deep thought and action by everyone in the NHS, patience and understanding from our patients, politicians and media organisations, and courage from everyone to soak up the inevitable failures and lapses along the way.*

*While “Zero Harm” is a bold and worthy aspiration, the scientifically correct goal is “continual reduction”. All in the NHS should understand that safety is a continually emerging property, and that the battle for safety is never “won”; rather, it is always in progress.*

*Quantitative targets and financial goals should not override protection of patients from harm. The Government, commissioners and health care providers should strive to strike a balance between minimising risk and allocating resources. Where scarcity of resources threatens to compromise safety, all NHS staff should raise concerns to their colleagues and superiors and be welcomed in so doing. This vigilance cannot come from regulation. It requires culture change and therefore countless, consistent and repeated messages and deeds over a period of years. It means living the values of the NHS Constitution. Goals and incentives should be clear, fully aligned, and focused on the interests of patients, with a high level of coherence across the system as a whole. The best way to reduce harm is for the NHS to embrace wholeheartedly a culture of learning.*

*Resource constraints will undoubtedly continue in the NHS. There are two ways to deal with this reality. One is by simply cutting budgets and thereby placing the burden on staff of caring with fewer resources. The other, better, way is through improvement – introducing new models of care and new partnerships among clinicians, patients and carers that can produce better care at lower cost. Only a culture of learning and improvement can follow that better way.*

# II. Leadership

## Recommendation

- 2. All leaders concerned with NHS healthcare – political, regulatory, governance, executive, clinical and advocacy – should place quality of care in general, and patient safety in particular, at the top of their priorities for investment, inquiry, improvement, regular reporting, encouragement and support.**

*Leadership is about mobilising the attention, resources and practices of others towards particular goals, values or outcomes. The continual reduction of patient harm requires clarity and constancy of purpose among all leaders, from the front-line to the Prime Minister and across the whole system.*

*Leadership requires presence and visibility. Leaders need first-hand knowledge of the reality of the system at the front line, and they need to learn directly from and remain connected with those for whom they are responsible. Culture change and continual improvement come from what leaders do, through their commitment, encouragement, compassion and modelling of appropriate behaviours.*

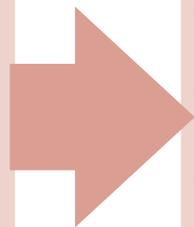
*Society in general and opinion formers in particular, including national and local media, politicians of all parties, and commentators, have an opportunity to engage in and facilitate and mature, open and constructive conversation about improving safety in the NHS. This includes harnessing the goodwill of all NHS staff and avoiding generalised criticism of their intentions, motivations, skill or dedication.*

Who	What
All staff and leaders of NHS-funded organisations	Every person working in NHS-funded care has a duty to identify and help to reduce risks to the safety of patients, and to acquire the skills necessary to do so in relation to their own job, team and adjacent teams. Leaders of health care provider organisations, managers, clinical leaders and Health Education England have a duty to provide the environment, resources and time to enable staff to acquire these skills.
All leaders and managers of NHS-funded organisations	All NHS leaders and managers should actively address poor teamwork and poor practices of individuals, using approaches founded on learning, support, listening and continual improvement, as well as effective appraisals, retraining and, where appropriate, revalidation.
NHS England	NHS England, through the NHS Leadership Academy, should designate a set of safety-leadership behaviours that can be used in leaders' hiring, in appraisals, in leadership development, and in promotion. The shift in leadership behaviour we think is required, and which could form the basis of a safety-leadership behaviour assessment, is provided in <b>Box 1</b> .
Leadership bodies <sup>2</sup> of NHS-funded organisations	All leadership bodies of NHS-funded health care providers should define strategic aims in patient safety, and should regularly review data and actions on quality, patient safety and continual improvement at their Board or leadership meetings.
Leadership bodies of NHS-funded organisations	Boards and leadership bodies should employ structures and processes to engage regularly and fully with patients and carers, to understand their perspectives on and contributions to patient safety.
Prime Minister and Government	Final responsibility for fostering a climate that supports learning and continual improvement in the NHS rests with the Prime Minister and the Government, who should so affirm repeatedly and forcefully.
Government and NHS organisations	The system should help patient representatives and community champions to become safety leaders, in part by offering them the opportunity to learn safety-leadership behaviours and skills.
Local Government Association	The Local Government Association should take lead responsibility for promoting better integration of the boundaries between health and social care in the interests of patient safety and encouraging local government to fulfil its scrutiny role effectively

<sup>1</sup> By Leadership Bodies we are referring to the variety of forms that different organisations use to run and lead themselves. These may be Boards, Committees or other structures.

**Box 1****The shift in behaviour from leaders across the system that we need to see:****Leadership behaviours that increase risk and make healthcare less safe:**

- Blame staff (even when they haven't been given the conditions for success)
- Fail to focus on the patient (often signalling instead that targets and costs are 'centre stage')
- Make bad news unwelcome (too often silencing it)
- Not heed signals and warnings that things are amiss
- Muffle the voice of the patients, their carers and their families and largely ignore their complaints
- Fail to listen to staff
- Diffuse responsibility and disguise who is in charge
- Offer no systematic support for improvement capability
- Game data and goals
- Lead by rules and procedures alone in a disengaged way
- Apply sanctions to errors
- Create fearfulness amongst colleagues and staff
- Ignore the development of the next generation of leaders
- Treat all problems as though they can be "fixed" with existing technologies or writing clearer procedures

**Leadership behaviours that reduce risk and make healthcare more safe:**

- Abandon blame as a tool
- Constantly and consistently assert the primacy of safely meeting patients' and carers' needs
- Expect and insist upon transparency, welcoming warnings of problems
- Recognise that the most valuable information is about risks and things that have gone wrong
- Hear the patient voice, at every level, even when that voice is a whisper
- Seek out and listen to colleagues and staff
- Expect and achieve cooperation, without exception
- Give help to learn, master and apply modern improvement methods
- Use data accurately, even where uncomfortable, to support healthcare and continual improvement
- Lead by example, through commitment, encouragement, compassion and a learning approach
- Maintain a clear, mature and open dialogue about risk
- Infuse pride and joy in work
- Help develop the leadership pipeline by providing support and work experiences to enable others to improve their own leadership capability
- Recognise that some problems require technical action but that others are complex and may require many innovative solutions involving all who have a stake in the problem

# III. Patient and public involvement

## Recommendation

3. **Patients and their carers should be present, powerful and involved at all levels of healthcare organisations from wards to the boards of Trusts.**

### **The patient voice should be heard and heeded at all times.**

*Patient involvement means more than simply engaging people in a discussion about services. Involvement means having the patient voice heard at every level of the service, even when that voice is a whisper. Evidence shows that patient safety improves when patients are more involved in their care and have more control. Patient involvement is crucial to the delivery of appropriate, meaningful and safe healthcare and is essential at every stage of the care cycle: at the front line, at the interface between patient and clinician; at the organisational level; at the community level; and at the national level. The patient voice should also be heard during the commissioning of healthcare, during the training of healthcare personnel, and in the regulation of healthcare services.*

*The goal is not for patients and carers to be the passive recipients of increased engagement, but rather to achieve a pervasive culture that welcomes authentic patient partnership – in their own care and in the processes of designing and delivering care. This should include participation in decision-making, goal-setting, care design, quality improvement, and the measuring and monitoring of patient safety. Patients and their carers should be involved in specific actions to improve the safety of the healthcare system and help the NHS to move from asking, “What’s the matter?” to, “What matters to you?” This will require the system to learn and practice partnering with patients, and to help patients acquire the skills to do so.*

Who	What
<b>All NHS Organisations</b>	Patients and their carers should be helped to establish effective relationships with their clinicians at every stage of their care, from GP surgery to hospital ward. (For example, there should be clear information about who is working on the ward and who will be each patient's primary nurse that day and night.)
<b>All NHS Staff</b>	Patients and their carers should always be given the opportunity to share their health concerns, histories, family situations, needs, preferences and hopes in order to help staff build effective partnerships during every stage of their care.
<b>All NHS Organisations</b>	Patients and (if the patient wishes) their carers should be involved as much as possible in their care planning. (For example, carers should be invited to and involved in ward rounds, multi-disciplinary meetings, Care Programme Approach meetings, discharge planning meetings and other significant clinical meetings.)
<b>Commissioners and providers</b>	NHS England, CCGs and provider organisations should ensure that a specific, named and recognised clinician, known to the patient, is responsible for the coordination of care for every patient at every phase of treatment regardless of setting.
<b>All NHS organisations</b>	Patients and their carers should always have access to and be given on request a clear, understandable and relevant summary of their health needs and preferences, which states how these needs will be met. This should include information about risks and alternatives and should allow them greater control of their healthcare.
<b>Leaders of NHS organisations</b>	It should always be clear who is responsible for patient safety concerns, and someone should be accessible to patients at every stage of treatment and 24 hours a day. When things do go wrong, incidents should be investigated appropriately and transparently, with the full involvement of the patient and their carers, who should be kept informed at every step of the way.
<b>Leaders of NHS organisations</b>	Patient feedback is instrumental to the measurement, maintenance and monitoring of safety; feedback should be collected as far as possible in real time and be responded to as quickly as possible.
<b>Leaders of NHS organisations</b>	Complaints provide vital information about the quality and safety of care and should be gathered and responded to in a timely way. The leaders of all healthcare organisations should continually improve their local complaint systems.
<b>Government</b>	We encourage further consideration of an independent national complaints management system that is easy to access and use, and that would also highlight and promote better practice and improvements in the NHS. We are aware that separate work is underway to look at the NHS complaints system, and we trust that appropriate recommendations will be implemented accordingly.
<b>All NHS organisations</b>	Patients and their carers should be represented throughout the governance structures of NHS-funded healthcare providers, for example by sitting on and actively participating in safety and quality committees. We encourage experimentation with full patient and carer membership on governing boards and on panels that hold boards to account. Patients and carers should be given appropriate support and training to take a full part in these structures, to understand safety science, and to contribute meaningfully.

## Box 2: Actions for Patients and Carers

We seek to engage everyone in improving safety, as far as they can and wish to be involved. This includes patients and carers. Below are our suggested actions for them:

- Patients and carers should seek to establish relationships with healthcare staff and know their names. Patients and carers should seek to build constructive relationships with their caregivers and develop mutual respect, honesty and trust.
- Patients and carers should try to share their histories, family situations, needs and hopes to help staff build true and effective partnerships during their care. They should aim as far as possible, to become co-producers of their care.
- Patients should share their goals, participate in creating plans for their care, engage their families and bring carers or relatives to visit, particularly during ward rounds and other clinical meetings.
- Patients and their carers should alert those working in healthcare when care is not meeting their needs or when they see a practice that they feel is not safe.
- Patients should, when they wish, advise leaders and managers by offering their expert advice on how things are going, on ways to improve, and on how systems work best to meet the needs of patients. This may mean giving time to attend meetings, participating in sessions to learn how the health care system works, learning the “inside” language that they will encounter, and learning to speak effectively to “authority”.

# IV. Staff

## Recommendation

- 4. Government, Health Education England and NHS England should assure that sufficient staff are available to meet the NHS's needs now and in the future. Healthcare organisations should ensure that staff are present in appropriate numbers to provide safe care at all times and are well-supported.**

*Everyone in the NHS should be able to come to work every day knowing they will be treated with respect, supported to do their work and expand their skills, and be appreciated for what they do.*

*Boards and leaders of provider organisations should take responsibility for ensuring that clinical areas are adequately staffed in ways that take account of varying levels of patient acuity and dependency, and that are in accord with scientific evidence about adequate staffing.*

*People should work in well-structured teams.*

Who	What
NICE	NICE should interrogate the available evidence for establishing what all types of NHS services require in terms of staff numbers and skill mix to assure safe, high quality care for patients.
All leaders of NHS-funded provider organisations	Staffing levels should be consistent with the scientific evidence on safe staffing, adjusted to patient acuity and the local context. (This includes, but is not limited to, nurse-to-patient staffing ratios, skill mixes between registered and unregistered staff, and doctor-to-bed ratios.) Boards and leaders of organisations should utilise evidence-based acuity tools and scientific principles to determine the staffing they require in order to safely meet their patients’ needs. They should make their conclusions public and easily accessible to patients and carers and accountable to regulators.
HEE, Government and NHS England	Health Education England should assure that they have commissioned the required training places to meet future staffing requirements working with Government and NHS England to ensure appropriate planning and resources.
All leaders and managers of NHS-funded provider organisations	The leaders of all NHS-funded organisations should foster good teamwork in care. They should ask teams to set challenging and measurable team objectives; facilitate better communication and coordination within and among teams; and encourage teams to regularly take time out to review their performance and how it can be improved.
All leaders and managers of NHS-funded provider organisations	Leaders and managers should actively support staff by excellent human resource practices, promoting staff health and well-being, cultivating a positive organisational climate, involving staff in decision-making and innovation, providing staff with helpful feedback and recognising good performance, addressing systems problems, and making sure staff feel safe, supported, respected and valued at work.
All leaders and managers of NHS-funded provider organisations	NHS organisations, working with professional regulators, should create systems for supportively assessing the performance of all clinical staff, building on the introduction of medical revalidation.
All leaders and managers of NHS-funded provider organisations	Each organisation should be expected to listen to the voice of staff, such as through department and ward level cultural and teamwork safety surveys, to help monitor the safety and quality of care and variation among units. (However, surveys of culture have not been scientifically validated as a performance metric and should not be used for this purpose.) Staff should all be free to state openly their concerns about patient safety without reprisal. There is no place for compromise agreements (“gagging clauses”) in such cases.

### Box 3: Actions for Staff

Many of our recommendations focus on actions needed by leaders, agencies and organisations. However, only the actions of front line staff, such as these listed here, can realise safe compassionate patient care and improvements to the healthcare system:

- Place the needs of patients, families and carers at the centre of all your work, treating them with courtesy and respect, and intervene if you see others who do not.
- Be a quality inspector, never knowingly passing on a defect, error or risk to a colleague or patient, putting things right where you can, and reporting everything, especially where you need help to put it right.
- Be willing to acknowledge and be open when something has gone wrong and make timely apologies and reparation where appropriate.
- Appreciate that your responsibility is not only to your patients but also to help continuously improve the healthcare system in collaboration with others.
- Treat your colleagues with respect and courtesy and seek to create supportive teams with common goals.
- Commit to learning about patient safety as a core professional responsibility and develop your own ability to detect problems.
- Be willing to speak up to leaders when you believe that a lack of skills, knowledge or resources places patients at risk of harm, and be willing to listen to others when they identify these risks.
- Celebrate and take pride in improvements to patient care.

#### A NOTE ON STAFFING RATIOS:

Our primary recommendation on staffing patterns is that NICE undertake as soon as possible to develop and promulgate guidance based on science and data. Such guidance, we assume, would include methods by which organisations should monitor the status of patient acuity and staff workload in real time, and make adjustments accordingly to protect patients and staff against the dangers of inadequate staffing. We also assume, and hope, that innovations will develop and continue in technologies, job designs, and skill mix that will and should change ideal staffing ratios, so that this role for NICE ought to be ongoing.

That said, and while NICE does its job, we call managers' and senior leaders' attention to existing research on proper staffing, which includes, but is not limited, to conclusions about ratios. For example, recent work suggests that operating a general medical-surgical hospital ward with fewer than one registered nurse per eight patients, plus the nurse in charge, may increase safety risks substantially. This ratio is by no means to be interpreted as an ideal or sufficient standard; indeed, higher acuity doubtless requires more generous staffing. We cite this as only one example of scientifically grounded evidence on staffing that leaders have a duty to understand and consider when they take actions adapted to their local context.

# V. Training and capacity building

## Recommendations

5. **Mastery of quality and patient safety sciences and practices should be part of initial preparation and lifelong education of all health care professionals<sup>3</sup>, including managers and executives.**
6. **The NHS should become a learning organisation. Its leaders should create and support the capability for learning, and therefore change, at scale, within the NHS.**

*The entire NHS should commit to lifelong learning about patient safety and quality of care through customised training for the entire workforce on such topics as safety science, quality improvement methods, approaches to compassionate care and teamwork.*

*The most powerful foundation for advancing patient safety in the NHS lies much more in its potential to be a learning organisation, than in the top down mechanistic imposition of rules, incentives and regulations. Collaborative learning through safety and quality improvement networks can be extremely effective and should be encouraged across the NHS. The best networks are those that are owned by their members, who determine priorities for their own learning.*

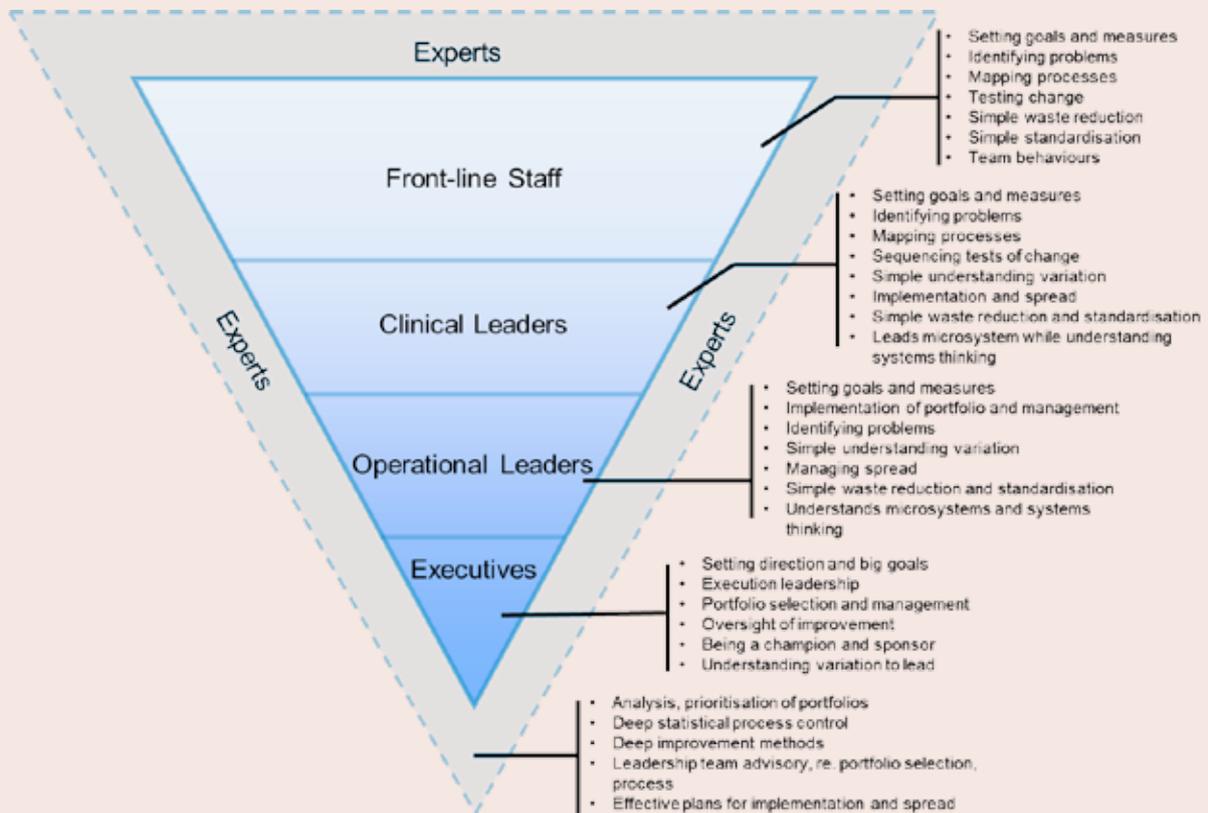
---

<sup>3</sup> Wherever this report refers to healthcare professionals we are explicitly including clinicians and non-clinicians alike who are involved in the healthcare system. This therefore includes managers, executives and relevant Governmental staff.

Who	What
Training and Education regulators, providers and HEE	The commissioners, regulators and providers of training and education for healthcare professionals (including clinicians, managers, Boards and relevant Governmental staff and leaders) should ensure that all healthcare professionals receive initial and ongoing education on the principles and practices of patient safety, on measurement of quality and patient safety, and on skills for engaging patients actively.
Education regulators, providers and HEE	Professional regulators (such as the GMC and NMC) should continue and build upon their good work to date with undergraduate and postgraduate education providers and Health Education England to ensure that medical and nursing undergraduates and postgraduates become thoroughly conversant with and skilful at approaches to patient safety and quality improvement.
NHS England and partners	NHS England working with partners (Royal Colleges, HEE, NHS Leadership Academy and others) should encourage and expand structured programmes to equip NHS leaders with an in-depth understanding of safety and improvement, and of managing the spread of innovations and good ideas within and among organisations.
All NHS organisations	NHS-funded health care providers should invest in building capability within their organisations to enable staff to contribute to improvement of the quality and safety of services to patients. <b>Box 4</b> illustrates one sound view of the capability which should be expected from each level in an organisation. A properly resourced capability programme must be in place within 12 months.
NHS England and Government	NHS England should be given the resources to support and learn from existing collaborative safety improvement networks and to sponsor the development of new regional or sub-regional collaborative networks across the country, perhaps aligned to and working with the new Academic Health Science Networks.
All NHS organisations	Every NHS organisation should participate in one or more collaborative improvement networks as the norm.
NHS England	Improvement networks should include processes for monitoring and evaluation by the networks together with NHS England in order to understand what works and to assure that best processes are spread and scaled to benefit all patients in the system.
NHS England	NHS England should organise a national system of NHS Improvement Fellowships, to recognise the talent of staff with improvement capability and enable this to be available to other organisations.

## Box 4

### Suggested improvement skills required for each group in a provider organisation



Adapted from Kaiser Permanente

# VI. Measurement and transparency

## Recommendations

7. Transparency should be complete, timely and unequivocal. All non-personal data on quality and safety, whether assembled by government, organisations, or professional societies, should be shared in a timely fashion with all parties who want it, including, in accessible form, with the public.
8. All organisations should seek out the patient and carer voice as an essential asset in monitoring the safety and quality of care.

*Patient safety cannot be improved without active interrogation of information that is generated primarily for learning, not punishment, and is for use primarily at the front line. Information should include: the perspective of patients and their families; measures of harm; measures of the reliability of critical safety processes; information on practices that encourage the monitoring of safety on a day to day basis; on the capacity to anticipate safety problems; and on the capacity to respond and learn from safety information. Data on staff attitudes, awareness and feedback are important resources to gain insights into staff concerns. However, it is counterproductive to use staff survey and attitude data as a performance management tool or to compare organisations.*

*Most health care organisations at present have very little capacity to analyse, monitor, or learn from safety and quality information. This gap is costly, and should be closed.*

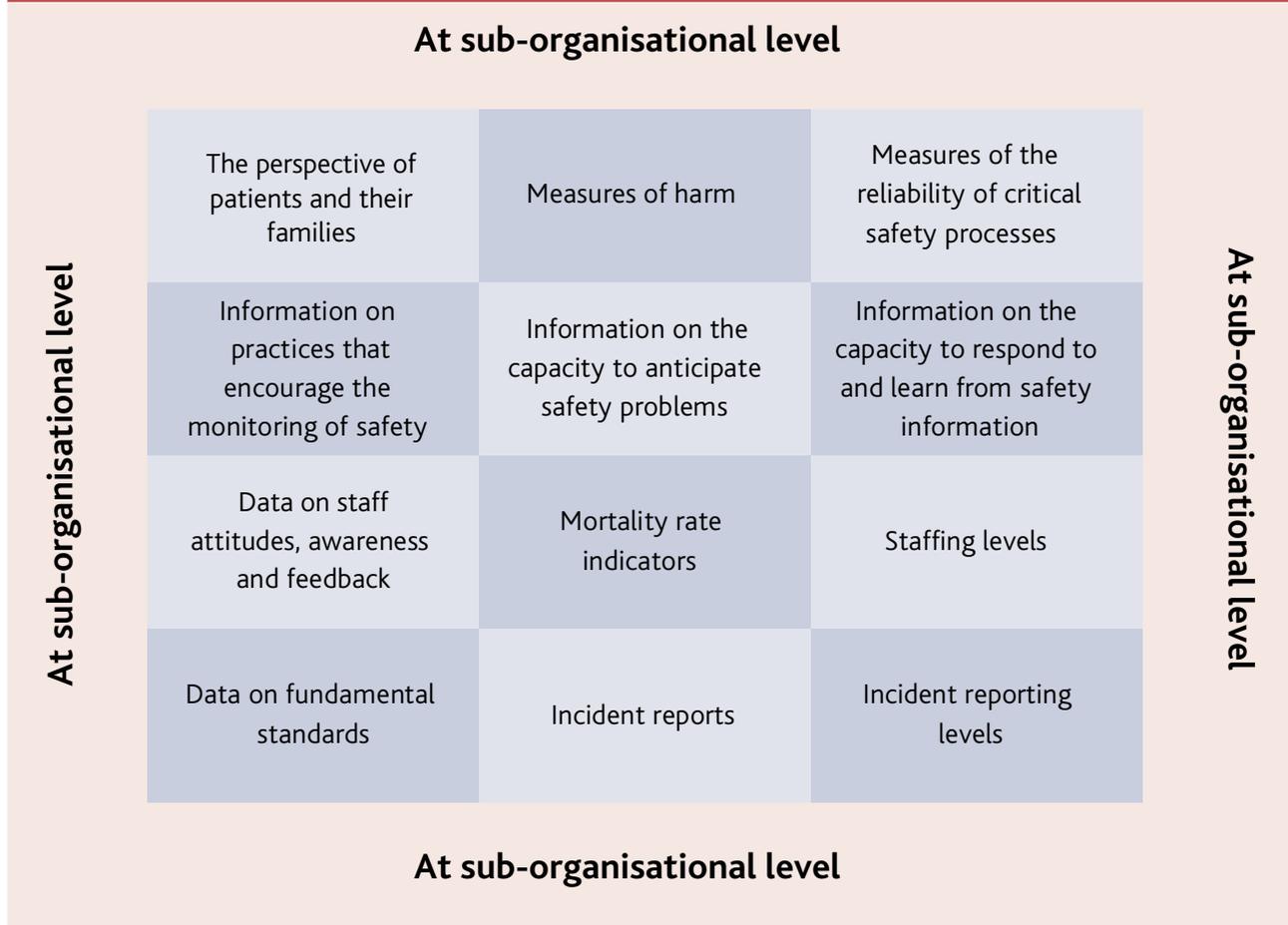
*We believe that aggregated data may camouflage variation within organisations that would be revealed by intelligent fine-grained analysis at local level. Leaders need to seek out variation within their organisations (not just among organisations) if safety and quality are to be effectively monitored and improved.*

*There is no single measure of safety, but early warning signals can be valuable and should be maintained and heeded.*

Who	What
<b>All healthcare system organisations</b>	Government, CQC, Monitor, TDA, HEE, NHS England, CCGs, professional regulators and all NHS Boards and chief executives should share all data on quality of care and patient safety that is collected with anyone who requests it, in a timely fashion, with due protection for individual patient confidentiality.
<b>All healthcare system organisations</b>	Government, CQC, Monitor, TDA, HEE, NHS England, CCGs, professional regulators and all NHS Boards and Chief Executives should include patient voice as an essential resource for monitoring and improving the safety and quality of care.
<b>Commissioners</b>	Commissioners should increase funding for NHS organisations to analyse and effectively use safety and quality information.
<b>NHS-funded healthcare providers</b>	Healthcare organisations should shift away from their reliance on external agencies as the guarantors of safety and quality and toward proactive assessment and accountability on their own part.
<b>All NHS-funded healthcare providers</b>	Providers should make use of peer review outside of formal systems – for example by partnering with other organisations – to facilitate learning.
<b>All NHS organisations</b>	Unless and until a better metric is developed, the NHS should use mortality rate indicators like the Hospital Standardised Mortality Rate or suitable alternatives as one of its ways to detect potentially severe performance defects worth investigating further. Mortality measurement should be used as a 'smoke detector' in a spirit of supportive and genuine inquiry, not used to generate league tables or similar comparisons.
<b>All NHS organisations</b>	Organisations should routinely collect, analyse and respond to local measures that serve as early warning signals of quality and safety problems such as the voice of the patients and the staff, staffing levels, the reliability of critical processes and other quality metrics. These can be 'smoke detectors' as much as mortality rates are, and they can signal problems earlier than mortality rates do.
<b>All NHS-funded provider organisations</b>	In addition to reporting aggregated data for the whole organisation, data on fundamental standards and other reportable measures, as required by CQC, should be reported by each ward, clinical department (and health care professional, where appropriate) within the Trust's Annual Quality Account. Leaders must understand the variation in their organisation, not just among organisations, in order to improve.

## Box 5

Illustrating some of the suite of indicators that should be used by NHS organisations to assess safety improvement and variation. This data must be considered at ward/unit or other appropriate sub-organisational level in order to reveal the variation within an organisation.



# VII. Structures and regulation

## Recommendation

- 9. Supervisory and regulatory systems should be simple and clear. They should avoid diffusion of responsibility. They should be respectful of the goodwill and sound intention of the vast majority of staff. All incentives should point in the same direction.**

*Delivering safe care is first and foremost the responsibility of providers, but having no regulation is not an option. Regulation should make clear the expectations that providers must meet, detect failings early, and take appropriate action when sub-standard care is found. The most effective regulation comes from a mixture of principles-based standards (developed by a process involving patients, carers and the public) and technical specifications where appropriate, supported by an inspection regime with true experts who are able to apply thoughtful judgement and the right actions in response.*

*The current NHS regulatory system is bewildering in its complexity and prone to both overlaps of remit and gaps between different agencies. It should be simplified.*

*The system needs to be agile, responsive and proportionate. This cannot be achieved through a series of prescriptive, technical standards that attempt to delineate between “acceptable” and “unacceptable” according to a tick-box or list. It can be achieved only through a well-resourced, highly coordinated, integrated and expert regulatory system employing intelligent and thoughtful inspection, able to apply both qualitative and quantitative judgement and take effective action when necessary. The same principles apply to oversight and performance management by commissioners and other supervisory bodies.*

*A high level of coherence is required across the system, with clear and fully aligned goals and incentives focused on the interests of patients at every level. All bodies involved in the oversight of health care providers need to actively avoid the creation of ‘priority thickets’ where providers become increasingly unclear about what they are doing and why, and where the goals they are supposed to achieve compete, conflict, or fail to cohere. Safety and quality stand the best chance when all of the drivers in the system – financial incentives, policies, regulatory strategies, use of competition, commissioning decisions, training, and organisational and professional norms – point in the same direction.*

Who	What
CQC and NHS England	CQC should hold Boards responsible for ensuring that recommendations from patient safety alerts are implemented promptly. NHS England should complete the re-design and implementation of a patient safety alerting system for the health care system in England. CQC should assure that organisations respond effectively to these alerts except in the rare circumstances where organisations can demonstrate that implementation of an alert is not in the interests of specific patient groups.
CQC, Monitor and the TDA	The regulatory complexity that Robert Francis identified as contributing to the problems at Mid Staffordshire is severe and endures, and the Government should end that complexity. Further large-scale structural reform is not desirable at present; however, it is imperative that CQC, Monitor and the Trust Development Authority commit to seamless, full, unequivocal, visible and whole-hearted cooperation with each other and with all other organisational and professional regulators, agencies and commissioners.
Government	Government should continually review the extent of this cooperation, and, if cooperation fails, Government should act immediately and decisively.
Regulators, HEE, professional societies, commissioners	CQC, Monitor, TDA, professional regulators, HEE, professional societies, Royal Colleges, commissioners and others should streamline requests for information from providers so that they have to provide information only once and in unified formats. The same is true of inspections.
CQC	CQC should act as the coordinating hub for intelligence about quality and safety of care.
NHS England	NHS England should promptly coordinate the development of an explicit description of the systems of oversight and controls of quality and safety relevant to different types of provider organisations, identify any vulnerabilities in those systems, and, working with others, take action to correct them.
CQC	CQC should develop the “fundamental standards” recommended by Robert Francis, using a process involving patients, carers and the public. Where appropriate these should be specified as human rights standards or principles rather than in technical terms, with compliance to be determined through thoughtful judgement on the part of expert inspectors, informed by metrics. The actions to be taken in the event of breaches of fundamental standards should be consistent with the principles of responsive regulation – i.e. using a pyramid of enforcement, ranging from persuasion through to punishment.
Government	An in-depth, independent review of structures and the regulatory system should be completed by the end of 2017, once current proposed changes have been operational for three years (see <b>Box 6</b> ).
Government	The Government should develop plans to allow for the permanent disqualification from relevant positions in the NHS of those at Director level or equivalent whose criminal liability is proven. This sanction is not to be used if someone is struggling in their current position or is facing intractable problems in achieving success. It is a sanction reserved for the worst conduct, and its availability as a sanction should act as a deterrent.
Government	The Government should ensure it is possible for healthcare support workers to receive training and development in order to meet clear codes of practice as is the case with medical, nursing and other professions.

## Box 6

**An independent review of NHS regulation should assess the weaknesses and strengths of the current system compared with various possible alternatives.**

The independent review should assess the following:	The system should be compared with the following alternatives as a minimum:
<ul style="list-style-type: none"> <li>• The extent to which the system is working</li> </ul>	<ul style="list-style-type: none"> <li>• Re-designation of CQC as a non-departmental public body accountable to Parliament rather than the Secretary of State</li> </ul>
<ul style="list-style-type: none"> <li>• Whether full and sincere cooperation and coordination have been achieved between the various agencies and bodies</li> </ul>	<ul style="list-style-type: none"> <li>• Merging regulators, or using an alternative model of non-government accreditation of healthcare organisations, perhaps modelled on the Joint Commission in the USA</li> </ul>
<ul style="list-style-type: none"> <li>• Whether the regulatory burden and cost is commensurate with the outcomes achieved</li> </ul>	<ul style="list-style-type: none"> <li>• Merging some or all of the organisational regulators so that responsibility for quality, patient safety, standards and outcomes are vested in one regulatory body and residual responsibilities are transferred to NHS England or other bodies (e.g. market and pricing responsibilities)</li> </ul>
<ul style="list-style-type: none"> <li>• Whether patients and those being regulated report that the system is effective and fair</li> </ul>	<ul style="list-style-type: none"> <li>• Consider if the current arrangements for public and community involvement and oversight of health and care, such as via HealthWatch and Health and Wellbeing Boards, are operating effectively and consider the case for revisiting earlier models like Community Health Councils</li> </ul>

# VIII. Enforcement

## Recommendation

- 10. We support responsive regulation of organisations, with a hierarchy of responses. Recourse to criminal sanctions should be extremely rare, and should function primarily as a deterrent to wilful or reckless neglect or mistreatment.**

*We considered very carefully the balance that must be achieved to support staff and organisations to learn from error and improve their practice with the need to assure accountability to the patient for egregious acts or omissions that cause death or serious harm. These two approaches are not mutually exclusive but unintended errors must be handled very differently from severe misconduct.*

*We believe that legal sanctions in the very rare cases where individuals or organisations are unequivocally guilty of wilful or reckless neglect or mistreatment of patients would provide deterrence whilst not impeding a vital open, transparent learning culture. Our proposals aim to place wilful or reckless neglect or mistreatment of all NHS patients on a par with the offence that currently applies to vulnerable people under the Mental Capacity Act.*

*We take full notice that a lack of regulation and sanctions was not the main problem in Mid Staffordshire. Indeed there already exists a series of robust sanctions and powers available to regulators such as CQC and the Health and Safety Executive. These should be used properly and the bodies with those powers resourced appropriately.*

*Ultimately, by far the greatest benefit to patient safety will be achieved by increasing the skills and the knowledge of the many rather than penalising the very few. We do not support the punishment of organisational leaders, Boards and chief executives, or others for poor performance that occurs for reasons beyond their control. We do recommend penalties for leaders who have acted wilfully, recklessly, or with a “couldn’t care less” attitude and whose behaviour causes avoidable death or serious harm, or who deliberately withhold information or provide misleading information.*

Who	What
Government	The Government should create a new general offence of wilful or reckless neglect or mistreatment applicable both to organisations and individuals. Organisational sanctions might involve removal of the organisation's leaders and their disqualification from future leadership roles, public reprimand of the organisation and, <i>in extremis</i> , financial sanctions but only where that will not compromise patient care. Individual sanctions should be on a par with those in Section 44 of the Mental Health Capacity Act 2005.
Government	It is absolutely vital that any new legislation avoid criminalising unintended errors. An individual should not be convicted of this new offence unless it can be shown the failure was the fault of the individual alone and the individual was acting in a reckless or wilful manner. Liability should be proportionate to past conduct for both individuals and organisations.
Government	The Government should make it an offence for a healthcare organisation to withhold or obstruct the provision of relevant information to a commissioner, regulator, inspector, coroner or other person with a legitimate duty in relation to quality and safety of care.
Government	The application of any of the criminal sanctions referred should be based on the liability criteria set out in <b>Box 7</b> .
Government and CQC	Where an incident qualifying as a Serious Incident (as defined by NHS England) occurs, CQC regulations should require that the patient or carers affected by the incident be notified and supported. We do not subscribe to an automatic 'duty of candour' where patients are told about every error or near miss, as this will lead to defensive documentation and large bureaucratic overhead that distracts from patient care. However, patients should be given all the information they ask for. Research should be commissioned to study how proactive disclosure of serious incidents, and the process of engaging with patients in relation to less serious incidents, can best be supported.
NHS-funded provider organisations and professional regulators	Employers need to improve their support of staff around implementing guidance on reporting of serious incidents and professional regulators should take appropriate action when required. Organisations should demonstrate that they have in place fully functional reporting systems for serious incidents, that staff know how to use them, that the systems are used, and that appropriate action is taken in response to incidents, including provision of appropriate support to the affected patients and their carers.
Government	We do not support the creation of a statutory duty for healthcare workers to report beliefs or suspicions about serious incidents to their employer, as this duty is adequately addressed in relevant professional codes of conduct and guidance.

## Box 7

Applying criminal sanctions, or indeed any sanctions, can be appropriate only in the very rare cases of neglect or wilful misconduct. In addition, where sanctions are considered appropriate we believe that the criteria below must be assessed and be met before those sanctions are applied:

Culpability	The extent to which the neglect or mistreatment of a patient is 'wilful', i.e. intentional, reckless or reflects a reckless 'couldn't care less' attitude.
Substitution	Whether the act or omission is unacceptable and would not be undertaken by a reasonable person or organisation in similar circumstances.
Degree of control for individuals	Only intentional behaviours under people's control (reflecting a reasonable degree of wilfulness or recklessness) should be sanctioned and <b>not</b> unintended error.
Degree of control for organisations	Only failure to create a reasonable safe system of care, or failure to act within its own system of care, or failure to adequately control those systems, or a reckless disregard for the well-being of patients should be sanctioned, and <b>not</b> when the organisation has taken all reasonable steps to achieve compliance.
Severity	The extent to the individual or organisation knowingly or recklessly puts the patient at risk of death or severe harm.
Liability should be proportionate to past performance	The test would be the degree to which the implicated actions are part of a pattern of ongoing and persistent failures to engage with, improve or address safety. This pattern will be taken particularly seriously where previous regulatory actions or managerial or supervisory warnings have been ignored or neglected by those concerned.
Liability should be proportionate to the level of control	The test would be the degree to which an individual (staff and/or directors) have control over the systems within which the implicated actions take place.

Formal guidance should be developed in the use of these liability criteria factors

## IX. Moving forward

Our aim was to develop a **small and cogent set of principles and actions** that, in our best judgment and on the basis of existing evidence, would help move the NHS as fast as possible toward better, safer care. In this, we have only partially succeeded. Our core recommendations are few, but the actions we suggest are more numerous than we initially intended. We were led there by the complexity of the NHS, itself, as a national endeavour. Many actors touch and shape the NHS. No one of them holds the keys to improvement. All have opportunities and duties to help, and the system can afford few bystanders.

Some of our recommendations have the hard edge of requirement and enforcement. For example:

- Providers should act on patient safety alerts, and regulators should ensure that they do.
- Transparency ought not to be optional.
- Staffing levels should be adequate, based on evidence.
- Sanctions should apply to reckless and wilful neglect or mistreatment of patients.

However, **our most important recommendations for the way forward envision the NHS as a learning organisation**, fully committed to the following:

- Placing the quality of patient care, especially patient safety, above all other aims.
- Engaging, empowering, and hearing patients and carers throughout the entire system and at all times.
- Fostering whole-heartedly the growth and development of all staff, including their ability and support to improve the processes in which they work.
- Embracing transparency unequivocally and everywhere, in the service of accountability, trust, and the growth of knowledge.

Every single actor in the landscape of the NHS should review these commitments and act on them. Especially important steps are the following:

**For Government and NHS England Leaders:**

1. State and restate the primacy of safety and quality as aims of the NHS: Assure prompt response to and investigation of early warning signals of serious problems, and, when needed, assure remedy.
2. Support investment in the improvement capability of the NHS.
3. Lead with a vision. Avoid the rhetoric of blame. Rely on pride, not fear.
4. Reduce the complexity of the regulatory system, and insist on total cooperation among regulators. If they do not cooperate, restructure them.

**For NHS Organisation Leaders and Boards:**

1. Listen to and involve patients and carers in every organisational process and at every step in their care.
2. Monitor the quality and safety of care constantly, including variation within the organisation.
3. Respond directly, openly, faithfully, and rapidly to safety alerts, early warning systems, and complaints from patients and staff. Welcome all of these.
4. Embrace complete transparency.
5. Train and support all staff all the time to improve the processes of care.
6. Join multi-organisational collaboratives – networks – in which teams can learn from and teach each other.
7. Use evidence-based tools to ensure adequate staffing levels.

**For System Regulators:**

1. Simplify, clarify, and align your requests and demands from the care system, to reduce waste and allow them to focus on the most important aims.
2. Cooperate fully and seamlessly with each other.

**For Professional Regulators and Educators:**

1. Assure the capacity and involvement of professionals as participants, teammates, and leaders in the continual improvement of the systems of care in which they work.
2. Embrace complete transparency.

**For NHS Staff and Clinicians:**

1. Participate actively in the improvement of systems of care.
2. Acquire the skills to do so.
3. Speak up when things go wrong.
4. Involve patients as active partners and co-producers in their own care.

**For Patients and Carers:**

1. As far as you are able, become active partners in your healthcare and always expect to be treated as such by those providing your healthcare.
2. Speak up about what you see – right and wrong. You have extraordinarily valuable information on the basis of which to make the NHS better.

The NHS in England can become the safest health care system in the world. That will require unified will, optimism, investment, and change. Everyone can and should help. And, it will require a culture firmly rooted in continual improvement. Rules, standards, regulations and enforcement have a place in the pursuit of quality, but they pale in potential compared to the power of pervasive and constant learning.

# Annex A: A note on our methodology

The Committee assembled was dominated in a majority by scientists – experts in organisational theory, quality improvement, safety and systems – and with a healthy minority of people currently in management positions within the NHS in England, though not deeply enmeshed in the time and occurrences of the Mid Staffordshire story itself. We included four Americans and one Scot, because of their deep familiarity with safety at the level of large health care systems, and, most important of all, three patient-advocates, people who, connected by their experiences of poor or variable patient care, have become vocal and eloquent voices for making sure that the NHS is seen and led through the eyes of patients and carers. To assure enough access to details of the Mid Staffordshire story and its context, we appointed a few Senior Advisors, upon whom the Committee could call as needed for information and suggestions.

We agreed to serve if, and only if, neither government nor NHS management nor, for that matter, any particular stakeholder group had or sought authority to censor or predetermine our findings. We had the Francis report, and a gracious Robert Francis, himself, to draw upon, but were under no obligation to endorse that report, or to accept, reject, or even comment upon any or all of its recommendations. We had a free hand.

Our deadlines were short and our methods respectful both of all the prior work of Francis and others and of the constrained, albeit enthusiastic, time of our busy members, all of whom volunteered without remuneration for this service. Our support from a Secretariat generously provided by the NHS was superb and facilitative. Our meetings were mostly biweekly and mostly virtual, with our American and Scottish members connected by videoconferences.

The bulk of the analyses was conducted by seven working parties established at our first meeting, each chaired by a Committee member, on the following topics: (1) Aims for Improvement, (2) Structures, (3) Measurement and Transparency, (4) Training and Capacity-Building, (5) Patient and Public Involvement, (6) Enforcement, and (7) Leadership. We established and maintained additional subsidiary efforts on (8) Staff and (9) Assuring Implementation. Working parties met between Committee meetings, and produced draft sections and recommendations under strict timelines, reviewed and discussed at the full Committee meetings. Senior Advisors and others made comments by invitation at nearly all Committee meetings.

Our recommendations were based on our best knowledge of the available evidence and our considered judgement.

We agreed to try to limit our final recommendations to a very small number, and to stay riveted on action as the goal. The “customers” for our recommendations, we agreed, would be several, including, but not limited to: (1) the Government (2) the senior executives of NHS England, (3) the leaders and staff of NHS-funded organisations (4) other clinical and executive leaders in the NHS, and (5) the public at large.

# Annex B: Letters

## Letter to Senior Government Officials and Senior Executives in the Health Service

Thank you for the opportunity to advise you and your colleagues on next steps toward a better and safer NHS. It is a privilege to be allowed to assist an organization for which I have such great respect, and it has been a pleasure to work with the talented and committed Advisory Group that you allowed me to assemble.

The full Report represents the unanimous views of the Advisory Group. I wish here to take the liberty of adding some personal comments and reflections for your consideration.

You are stewards of a globally important treasure: the NHS. In its form and mission, guided by the unwavering charter of universal care, accessible to all, and free at the point of service, the NHS is a unique example for all to learn from and emulate. Faults are to be expected in any enterprise of such size and ambition, and, as you know, the nation's leaders have the dual duty to continually, unblinkingly recognize and reduce those faults and at the same time to maintain and build confidence in the grand vision of the NHS.

The Mid Staffordshire tragedy and its sequellae offer the chance to do both. Thanks to Robert Francis, the nation can see directly some important problems, worth solving, not just in Mid Staffordshire but throughout the NHS. Our Report describes some of those problems. Among them are a partial loss of focus on quality and safety as primary aims, inadequate openness to the voices of patients and carers, insufficient skills in safety and improvement, staffing inadequate for patients' needs, and very unhelpful complexity and lack of clarity and cooperation among regulatory agencies. You, as leaders, can help to remedy every one of those problems and the others that we name. I hope and strongly suspect that you will do so.

In trying to achieve remedy, your most certain and productive pathways will be built on the enormous strengths of the NHS – its people, their commitment, its charter, much of its track record, and the affection and wisdom of patients and carers. I hope that you will invest even more than ever before in learning, growth, development, ambition, and pride. This is the route that can make the NHS a "learning organization" in every sense of the term, and it can unleash momentum for improvement that no simple, top-down, control-oriented, requirement-driven culture ever can.

This is not to excuse or ignore the whole story, as Robert Francis and we understand it. Very occasionally at the root of harm do lie willful, reckless behaviors or neglect that cannot be tolerated, any more than reckless driving can be. There is an important role for responsive regulation by experts, enforcement, and consequences in such circumstances. It is equally important to be alert to early warning signs of possible serious quality and safety problems, and to investigate and act on them. Your recent advisors – Robert Francis, Sir Bruce Keogh, and we – do converge in our recommendations for clarity, timeliness, and reliability in taking action when such alarms sound.

But, as I think you know, this – acting on rare and outlying behaviors and on exceptional cases of poor performance – though necessary, will not create an overall far safer and better NHS; it cannot.

A culture of learning can . And the likelihood of such a culture's thriving in the NHS depends, more than on anything else, on how you, the senior leaders, behave, speak, and invest.

This report is longer than I had hoped it would be. We had no choice; the NHS is complex and actors are inescapably interdependent. As you will see, however, we offer one distillation that you may wish to keep in mind as you peruse the whole. These are four guiding principles that, I suggest, should inform every step you take in these matters – in what you think, say, and do:

- Place the quality and safety of patient care above all other aims for the NHS. (This, by the way, is your safest and best route to lower cost.)
- Engage, empower, and hear patients and carers throughout the entire system, and at all times
- Foster wholeheartedly the growth and development of all staff, especially with regard to their ability and opportunity to improve the processes within which they work.
- Insist upon, and model in your own work, thorough and unequivocal transparency, in the service of accountability, trust, and the growth of knowledge.

Time and again in our Group's deliberations, every member used the word "culture" to diagnose both the faults of and the possibilities for the NHS. I urge you to focus on the culture that you want to nurture: buoyant, curious, sharing, open-minded, and ambitious to do even better for patients, carers, communities, and staff pride and joy. If you read our recommendations carefully, and act on them, I believe that you will have set your compass right.

Don Berwick

## Letter to the people of England

Your government and the leaders of the English National Health Service did me the honor earlier this year of asking me to assemble and chair an Advisory Group to recommend some important actions that leaders, clinicians, professional bodies, government agencies and others could take to improve the quality and safety of care in the NHS.

I took that assignment with hesitation and humility. I am an American, not English, and cannot claim the detailed knowledge and cultural sensibility that would lead to the best advice. But I was given a chance to recruit a wonderful group of people as the Advisory Group – most of whom have direct experience of your NHS while the rest admire it from afar – and who worked hard together to understand the problems and craft good suggestions. These included scholars whose careers have been devoted to studying safety and the conditions for excellence, clinicians and managers who know the NHS well, and, most important, patient representatives who could draw on their own experiences and their families', some tragic and hopefully never-to-be-repeated. This group gave me confidence that we would stay on the right track.

Of course, as you know, one of the main motivations for this assignment was the notorious "Mid Staffordshire" tragedy, in which serious problems in a hospital developed that led to avoidable patient deaths and injuries. That event spawned over two years of inquiry by Robert Francis, and, in early, 2013, the "Francis Report," with over 1700 pages and 290 recommendations. Your Government and NHS leaders turned to our Advisory Group for ideas on how to accelerate improvement of care in the wake of Mid Staffs. Ours was not the only group at all; lots of teams and leaders were tackling the same concerns while we did our work.

Our full report is now here for you and anyone else to see. It contains some technical material regarding regulation, improvement science, and management, but I hope that lay readers will find it comprehensible and sensible. Toward that end, I would like to share a few personal reflections for you possibly to ponder, as follows:

You will have read much in the public press that may alarm you about the patient care in the English NHS. After all, things did go quite wrong at Mid Staffs, and, like others, we believe that problems in care often occur throughout the NHS. In that, however, I assure you that the same can be said of every health care system in the world. Health care is complicated, and, even when the staff and clinicians are doing their very best (which is most of the time), errors occur and problems arise for patients that no one intends.

What you do have in the NHS is something that most other nations in the world don't have: a unified system of care that is completely capable of identifying its problems, admitting them, and acting to correct them. That is the process now underway; that is the process that led your leaders to convene our Advisory Group; and that is the process that can and, I believe, will help the English NHS to emerge over time as one of the safest health care systems in the world.

That is not easy. And it gets even harder if the staff of the NHS experience a culture of fear, blame, recrimination, and demoralization. I hope that you resist such general negativity, in yourself and anyone else, and instead clearly point the way with energy and optimism toward the care that you and I want, and that the vast majority of people who work in the NHS want to offer.

In the Mid Staffs story and elsewhere, there are occasional cases of people who willfully or recklessly did some harm. That, of course, cannot be tolerated, and occasionally strong measures of enforcement are needed. There are also clearly occasional organizations for which early warning signals suggest that serious problems may exist. In such cases, your government and NHS leaders can and should promptly investigate, reach conclusions, and act.

But enforcement, even though needed, is not really the route to an overall ever better NHS – the NHS you want. Instead, our report says, bet on “learning.” The English NHS is capable of vast and continual improvement of safety, quality, patient-centeredness, and even cost, if, and maybe only if, everyone involved engages in learning every day. The questions that come up in such a culture are ones like this:

- Whom do we serve, and what do they really want and need?
- How are we doing at meeting those needs?
- How do we know?
- What could we do differently that would do that better?
- Who knows something – a better model, maybe – that we could put to work here?

Imagine an NHS where everyone, all the time, was part of that journey, and has the respect and tools to improve. That’s what our Group recommends, in part, as you will see in this report.

We are recommending four main principles to guide everyone in trying to build an even better “learning NHS.” Here they are:

- Place the quality and safety of patient care above all other aims for the NHS. (This, by the way, is your safest and best route to lower cost.)
- Engage, empower, and hear patients and carers throughout the entire system, and at all times
- Foster wholeheartedly the growth and development of all staff, especially with regard to their ability and opportunity to improve the processes within which they work.
- Insist upon, and model in your own work, thorough and unequivocal transparency, in the service of accountability, trust, and the growth of knowledge.

In all of that you – patients, carers, and citizens – have a vital and exciting role to play. Your voice is key to the future. I hope that this report will give you more confidence in speaking up everywhere and all the time in a vital NHS, and will give those who care for you and want to help you the confidence and skills to invite you, hear you, and welcome you into authentic partnership.

Don Berwick

## Letter to the clinicians, managers, and all staff of the NHS

First of all, thank you. For the nearly three decades that I have been able to observe and work with the NHS, nothing has impressed me more than you – the workforce of 1.3 million people who are trying to make real a vision of a vital, universal health care system, accessible to all, and free at the point of service. Your nation’s commitment to health care as a human right and to healing as a shared mission is second to none in the world. And all of that is possible through you; only through you.

But, it gets rough sometime, doesn’t it? Because you work in a publicly led and publicly funded system of care, you operate under a spotlight more intense than most professional communities ever do. And truth to tell, it doesn’t always go so well. Every experienced clinician knows what it feels like to be involved in an error in care, despite one’s very best efforts. And the abstract concept of a “system” that fails has concrete meaning in the life of every doctor, nurse, or therapist who couldn’t find a crucial test result, became exhausted when staffing was inadequate to meet patients’ needs, or watched a patient get an infection in a hospital.

When things go especially badly, as happened, for example, in Mid Staffordshire, and public and private sentiment heats up, it can feel especially rough. And, at its worst, problems like that can hurt morale, as people lose sight of how great the mission is and of how hard you are trying to do what’s right.

I was asked by Government and your senior leaders to chair an Advisory Group to recommend what can be learned from recent instances of quality problems in the NHS, and how the system can more rapidly and certainly aim for improvements in patient care and safety. The Group comprised scholars with a special interest in health care quality, leaders familiar with the workings of the NHS, and, most important, patient representatives with personal experiences of both excellence and problems in care.

The resulting report represents our best effort at identifying changes that could help the English NHS become even more the effective, safe, and patient-centered system that you who work in the Service want it to be.

We have made numerous recommendations, some of which reflect the need to tighten surveillance of and response to serious problems in care, which need systemic fixes to help protect patients. As you well know, safety in any sector – aviation, roads, or health care – sometimes requires a commitment to reliability and adherence to proper standards. And some standards should be seriously enforced; the risks of not doing that are too great. In addition, when early warning signs from patients, carers, staff, or data suggest a possibility that serious problems exist in quality and safety, the Government and leaders of the NHS are duty-bound to investigate, reach sound conclusions, and take prompt action.

But, as you probably also know, real, sustainable, active improvement depends far more on learning and growth than on rules and regulations. And that is the balance we are suggesting that the NHS seek to strike – between the hard guardrails that keep things in proper order and the culture of continual learning that helps everyone to grow. A phrase that I believe I heard first in England captures that sense: “All Teach – All Learn.” In such a culture, measurement is not a threat, it is a resource; ambition is not stressful, it is exciting; defects are seen as opportunities to learn; and curiosity abounds.

We are recommending four guiding principles, among others, to help the English NHS get better faster, and I urge you to think about these and ask how you can help incorporate them into your own daily work.

- Place the quality and safety of patient care above all other aims for the NHS. (This, by the way, is your safest and best route to lower cost.)
- Engage, empower, and hear patients and carers throughout the entire system, and at all times.

- Foster wholeheartedly the growth and development of all staff, especially with regard to their ability and opportunity to improve the processes within which they work.
- Insist upon, and model in your own work, thorough and unequivocal transparency, in the service of accountability, trust, and the growth of knowledge.

Our Group is urging leaders and the public at large to study, grasp, and act on these ideas, as well. We would hope to see the English NHS emerge as a vital “learning organization,” with you, who work in and for it, experiencing pride and joy in pursuing the great mission you have chosen: to heal.

Don Berwick

# Annex C: List of Advisory Group Members

The National Advisory Group on the Safety of Patients in England who contributed to this report:

Don Berwick KBE, MD, MPP, FRCP President Emeritus and Senior Fellow, Institute for Healthcare Improvement

Jo Bibby, Director of Strategy, Health Foundation

Maureen Bisognano, President and CEO, Institute of Healthcare Improvement

Ian Callaghan, Service User Lead, My Shared Pathway, Patient Representative

David Dalton, CEO, Salford Royal NHS Trust Foundation

Mary Dixon-Woods, Professor of Medical Sociology, University of Leicester

Jan Gould, Asthma UK, Patient Representative

Carol Haraden, Vice President, Institute for Healthcare Improvement

Jean Hartley, Professor of Public Leadership, Open University

Elaine Inglesby-Burke, Director of Nursing, Salford Royal NHS Trust Foundation

Lucian Leape, MD, Adjunct Professor of Health Policy, Harvard School of Public Health

Jenny Leggot, Deputy Chief Executive, Director of Nursing, Midwifery and Operations, University Hospital NHS Trust

Jason Leitch, Clinical Director, Health and Social Care Directorate, NHS Scotland

James Reason, CBE, Professor Emeritus, University of Manchester

Lisa Richards-Everton, Patient Representative

Stephen Singleton, CE and Medical Director, Zero Tolerance Healthcare

Charles Vincent, Director, Imperial College Centre for Patient Safety and Service Quality

